

MR# 352226

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February 20, 2013



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Bovine Corneal Opacity and Permeability Test (BCOP Test) with a Substituted butyrolactam (A)

Dear Section 8(e) Coordinator:

[REDACTED] is submitting Results of a Bovine Corneal Opacity and Permeability Test (BCOP Test) with a substituted butyrolactam (A), [REDACTED], conducted by [REDACTED].

Summary:

The potential of [REDACTED], to cause serious damage to the eyes was assessed by a single topical application of 750 μ L of the undiluted test substance to the epithelial surface of three isolated bovine corneas.

Three corneas were treated with the test substance for 10 minutes followed by a 2-hours post-incubation period. Based on changes in corneal opacity and permeability (relative to the control corneas), an *In Vitro* Irritancy Score was determined.

Corneal opacity was measured quantitatively as the amount of light transmission through the cornea. Permeability was measured quantitatively as the amount of sodium fluorescein dye that passes across the full thickness of the cornea. Both measurements were used to calculate an *In Vitro* Irritancy Score of the test substance.

The BCOP test showed the following results:

Test substance	Mean Opacity Value	Mean Permeability Value	Mean <i>In Vitro</i> Irritancy Score
[REDACTED]	30.1	2.402	66.1
Negative control	-0.2	0.001	-0.2
Positive control	122.7	1.935	151.8



These results indicate the potential to seriously damage the eye.

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[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures